

EXHIBIT A

Ragnvald Mjanger

Reliance List
in Addition to Materials Referenced in Report

Medical Literature

Agostini A, et al. [Pop 12,280] Immediate complications of tension-free vaginal tape (TVT): results of a French survey. <i>Eur J Obstet Gynecol.</i> 2006; 124:237-239.
Aigmuller T, et al. [10 yr fu] Ten-year follow-up after the tension-free vaginal tape procedure. <i>Am J Obstet Gynecol.</i> 2011; 205:496.e1-5.
Albo M, Richter, Zimmern, Moalli, Sirls. - NEJM - SISTEr study - Burch Colposuspension versus Fascial Sling to Reduce Urinary Stress Incontinence. <i>N Engl J Med</i> 2007;356:2143-55.
Amid PK. Biomaterials for abdominal wall hernia surgery and principles of their applications. <i>Langenbecks Arch Chir</i> (1994) 379:168-171
Amid PK. Classification of biomaterials and their related complications in abdominal wall hernia surgery. <i>Hernia</i> :1997;1:15-21.
Angioli R, Plotti F, Muzii L, Montera R, Panici PB, Zullo MA. Tension-free vaginal tape versus transobturator suburethral tape: five-year follow-up results of a prospective, randomised trial. <i>Eur Urol</i> 2010;58:671-677.
Boukerro. Objective analysis of mechanical resistance of tension-free devices. <i>European Journal of Obstetrics & Gynecology and Reproductive Biology</i> 124 (2006) 240-245
Boukerrou M, et al. Study of the biomechanical properties of synthetic mesh implanted in vivo. <i>Eur J Obstet Gynecol Reprod Biol</i> (2007) 134:262-267
Brubaker L, et al. Adverse events over two years after retropubic or transobturator midurethral sling surger: Findings from the trial of midurethral slings (TOMUS) Study. <i>Am J Obstet Gynecol</i> 2011;205:498e.1-6
Cassidenti A. The crushing of innovation for treating female pelvic floor disorders: A Story of "Lead or be Led." <i>OBG Management</i> 2016; 28(4): 9-14
Celebi - [Pop 563, 5 yrs fu] Results of the TVT procedure for treatment of female SUI: a 5 year follow-up study; <i>Arch Gynecol Obstet</i> (2009) 279:463-467
Collinet P. et al. The Safety of the Inside-Out Transobturator approach for transvaginal tape (TVT-O) treatment in stress urinary incontinence: French registry data on 984 women. <i>Int Urogynecol J</i> (2008) 19:711-715
Costantini. [Pop 87, median 100 mos fu] Long-term efficacy of the trans-obturator and retropubic MUS for SUI: update from a randomized clinical trial; <i>World J Urol</i> , DOI 10.1007/s00345-015-1651-z, 2015
Cox A, Herschorn S, Lee L. [Nat Rev Urol] Surgical management of female SUI: is there a gold standard? <i>Nat Rev Urol.</i> 2013 Feb;10(2):78-89.
Cresswell J, et al. [pop 118, mean 6.6 yrs fu] Long-term evaluation of tension-free vaginal tape (TVT) outcomes for a UK Surgeon: Objective assessment and patient satisfaction questionnaires. <i>British Journal of Medical and Surgical Urology</i> (2008) 1, 58-62.
Dietz HP, et al. [Pop 68, median 1.6 yrs fu] Does the Tension-Free Vaginal tape stay Where you Put It? <i>Am J Obstet Gynecol</i> 2003; 188:950-3
Dietz HP, et al. Mechanical properties of urogynecologic implant materials. <i>Int Urogynecol J</i> (2003) 14:239-243.
Drutz H. IUGA guidelines for training in female pelvic medicine and reconstructive pelvic surgery (FPM-RPS). Updated Guildelines 2010. <i>Int Urogynecol K=J</i> 2010; 21: 1445-1453.
Dyrkorn OA, Kulseng-Hanssen S, Sandvik L. TVT compared with TVT-O and TOT: Results from the Norwegian National Incontinence Registry; <i>Int Urogynecol J</i> (2010) 21:1321-1326.
Falconer C. Clinical Outcome and Changes in Connective Tissue Metabolism After Intravaginal Slingplasty in Stress Incontinence Women. <i>Int Urogynecol J</i> 1996; 7: 133-137
Ford AA, et al. (Cochrane Review[FULL]) Mid-urethral sling operations for stress urinary incontinence in women. <i>The Cochrane Library</i> 2015, Issue 7
Groutz A, Rosen G, Cohen A, Gold R, Lessing JB, Gordon D. [Pop 52, 10 yr fu] Ten-year subjective outcome results of the retropubic tension-free vaginal tape for treatment of stress urinary incontinence. <i>J Minim Invasive Gynecol</i> (2011) 18:726-729

Medical Literature

Han J-Y, Park J, Choo M-S. [Pop 88, 12 yr fu] Long-term durability, functional outcomes, and factors associated with surgical failure of tension-free vaginal tape procedure. <i>Int Urol Nephrol</i> (2014) 46:1921-1927
Hansen, Gradel. [Danish Registry] Reoperation for urinary incontinence-a nationwide cohort study, 1998 thru 2007; <i>Am J Obstet Gynecol</i> 2016;214:263.e1-8
Heinonen P. [Pop 191, mean 10.5 yrs fu] Tension-free vaginal tape procedure without preoperative urodynamic examination: Long-term outcome. <i>Int J Urol</i> 2012; 19:1003-1009
Holmgren S, Nilsson. [Pop 760, 8 yr fu] Long-Term Results with Tension-Free Vaginal Tape on Mixed and Stress Urinary Incontinence. <i>Obstetrics & Gynecology</i> ; Vol. 106, No. 1, July 2005
Jelovsek J, et al. [Pop 72, mean 62 mos fu] Randomized trial of laparoscopic Burch colposuspension versus tension-free vaginal tape: long-term follow up. <i>BJOG</i> 2008; 115: 219-225.
Jonsson Funk M. Sling Revision/ Removal for Mesh Erosion and Urinary Retention: Long-Term Risk and Predictors. <i>Am J Obstet Gynecol.</i> 2013; 208(1): 73.e1-73.e7
Karlovsy M. Synthetic Biomaterials for Pelvic Floor Reconstruction. <i>Current Urology Report</i> 2005; 6:376-384
Kenton K, Zyczynski H, Sirls LT, Richter HE, et al. (TOMUS published) 5-Year Longitudinal Followup after Retropubic and Transobturator Mid-urethral slings. <i>The Journal of Urology</i> , Vol. 193, 203-210, January 2015.
Kersey J. The gauze hammock sling operation in the treatment of stress incontinence. <i>British Journal of Obstetrics & Gynecology</i> 1983; 90:945-949.
Kirby A. Midurethral slings: which should I choose and what is the evidence for use? <i>Curr Opin Obstet Gynecol</i> 2015; 27: 359-365
Kuuva N, Nilsson. [Pop 1455, 2 mo fu] A nationwide analysis of complications associated with the tension-free vaginal tape (TVT) procedure. <i>Acta Obstet Gynecol Scand</i> 2002; 81: 72-77
Laurikainen E, Valpas A, Aukee P, Kivelä A, Rinne K, Takala T, Nilsson CG. [Pop 254, 5 yr fu] Five-year results of a randomized trial comparing retropubic and transobturator midurethral slings for stress incontinence. <i>Eur Urol</i> (2014) 65:1109-1114
Li B, Zhu L, Lang JH, Fan R, et al. [Pop 55, 7 yr fu] Long-term outcomes of the tension-free vaginal tape procedure for female stress urinary incontinence: 7-year follow-up in China. <i>J Minim Invasive Gynecol.</i> 2012 Mar-Apr;19(2):201-5.
Liapis A, Bakas P, Creatsas G. [Pop 65, 5 & 7 yr fu] Long-term efficacy of tension-free vaginal tape in the management of stress urinary incontinence in women: efficacy at 5- and 7-year follow-up. <i>Int Urogynecol J Pelvic Floor Dysfunct</i> (2008) 19:1509-1512
Lo TS, et al. Ultrasound assessment of mid-urethra tape at three-year follow-up after tension-free vaginal tape procedure. <i>Urology</i> 63:671-675, 2004
Lukacz ES, et al. [Pop 54, 1 yr fu] The effects of the tension-free vaginal tape on proximal urethral position: a prospective, longitudinal evaluation. <i>Int Urogynecol J Pelvic Floor Dysfunct.</i> 2003 Aug;14(3):179-84.
Moalli PA, et al. Tensile Properties of five commonly used mid-urethral slings relative to the TVT. <i>Int Urogynecol J</i> (2008) 19:655-663.
Moir J. The Gauze-Hammock Operation. A Modified Aldrige Sling Procedure. <i>The Journal of Obstetrics and Gynaecology of the British Commonwealth</i> Vol. 75, No. 1 January 1968
Nager C. Midurethral Slings: Evidence-based Medicine vs. The Medicolegal System. Accepted Manuscript to appear in: <i>American Journal of Obstetrics and Gynecology</i> ; 2016 doi: 10.1016/j.ajog.2016.04.018
Nager C. Midurethral Slings: Evidence-Based Medicine vs. The Medicolegal System. <i>American Journal of Obstetrics and Gynecology</i> 2016 DOI: 10.1016/j.ajog.2016.04.018
Nguyen J. [Pop 4,142] Perioperative Complications and Reoperations After Incontinence and Prolapse Surgeries Using Prosthetic Implants, <i>Obstet Gynecol.</i> 2012 Mar;119(3):539-46

Medical Literature

Nichols DH. The Mersilene Mesh Guaze-Hammock for Severe Urinary Stress Incontinence. <i>Obstet Gynecol</i> 1973; 41(1): 88-93.
Nilsson C. [7 yr fu] Seven-Year Follow-up of the Tension-Free Vaginal Tape Procedure for Treatment of Urinary Incontinence. <i>Obstet Gynecol</i> (2004) 104, 1259-1262
Nilsson C. Creating a gold standard surgical procedure: the development and implementation of TVT. <i>Int Urogynecol J</i> 2015; 26(4): 467-469
Nilsson C. Long-term Results of the Tension-Free Vaginal Tape (TVT) Procedure for Surgical Treatment of Female Stress Urinary Incontinence. <i>Int Urogynecol J</i> 2001; (Suppl 2): S5-S8
Nilsson CG, Palva K, Aarnio R, Morcos E, Falconer C. [Pop 58, 17 yrs fu] Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. <i>Int Urogynecol J</i> (2013) 24: 1265-1269
Nilsson CG. Eleven years prospective follow-up of the tension-free vaginal tape procedure for treatment of stress urinary incontinence. <i>Int Urogynecol J</i> (2008) 19: 1043-1047
Nilsson M, et al. (Swedish Registry) [Pop 3334, 12 mo fu] Female urinary incontinence: patient-reported outcomes 1 year after midurethral sling operations. <i>Int Urogynecol J</i> . 2012 Oct;23(10):1353-1359.
Novara G, Galfano A, Boscolo-Berto R, Secco S, Cavalleri S, Ficarra V, Artibani W. [meta-analysis] Complication rates of tension-free midurethral slings in the treatment of female stress urinary incontinence: a systematic review and meta-analysis of randomized controlled trials comparing tension-free midurethral tapes to other surgical procedures and different devices. <i>Eur Urol</i> 53 (2008):288-309
Ogah. Minimally invasive synthetic suburethral sling operations. <i>Cochrane Review [Abstract] Cochrane Database Review; The Cochrane Library</i> 2009, Issue 4
Olsson I, Abrahamsson AK, Kroon UB. Long-term efficacy of the tension-free vaginal tape procedure for the treatment of urinary incontinence: a retrospective follow-up 11.5 years post-operatively. <i>Int Urogynecol J</i> (2010) 21:679-683
Pandit A. Design of surgical meshes - an engineering perspective. <i>Technology and Health Care</i> 2004; 12: 51-65
Petros P. Creating a gold standard surgical device. Scientific discoveries leading to TVT and beyond. <i>Int Urogynecol J</i> DOI 10.1007/s00192-015-2639-3
Prien-Larsen JC, Hemmingsen L. [Pop 316, 5 yr fu] Long-term outcomes of TVT and IVS operations for treatment of female stress urinary incontinence: monofilament vs. multifilament polypropylene tape. <i>Int Urogynecol J Pelvic Floor Dysfunct</i> (2009) 20:703-709
Reich A, Kohorst F, Kreienberg R, Flock F. [7 yr fu] Long-term results of the tension-free vaginal tape procedure in an unselected group: a 7-year follow-up study. <i>Urology</i> (2011) 78:774-777
Richter, Brubaker, Zimmern, Sirls (UITN) SISTEr [Pop 482, 7 yr fu] Patient Related Factors Associates with Long-Term Urinary Continence After Burch Colposuspension and Pubovaginal Fascial Sling Surgeries. <i>J Uro</i> , Vol. 188, 485-489, August 2012
Schimpf MO, Rahn DD, Wheeler TL et al. (published) [meta-analysis] Sling surgery for stress urinary incontinence in women: a systematic review and meta-analysis. <i>Am J Obstet Gynecol</i> (2014) 211:71.e1-71.e27
Schiotz H. [Pop 33,10 yr fu] Ten-year follow-up after conservative treatment of stress urinary incontinence. <i>Int Urogynecol J</i> (2008) 19:911-915
Schraffordt Koops. [Pop 634, 2 yr fu] Quality of life before and after TVT, a prospective multicenter cohort study, results from the Netherlands TVT database; <i>BJOG</i> 2006; 113:26-29
Schraffordt Koops. The effectiveness of tension-free vaginal tape (TVT) and quality of life measured in women with previous urogynecologic surgery; Analysis from the Netherlands TVT database; <i>American Journal of Obstetrics and Gynecology</i> (2006) 195, 439-44

Medical Literature

Serati M, Ghezzi F, Cattoni E, Braga A, Siesto G, Torella M, Cromi A, Vitobello D, Salvatore S. [Pop 58, but 10 yrs fu] Tension-free vaginal tape for the treatment of urodynamic stress incontinence: efficacy and adverse effects at 10-year follow-up. <i>Eur Urol</i> (2012) 61:939-946
Shao U, et al. [Pop 24, median 57 mo fu] Tension-free vaginal tape retropubic sling for recurrent stress urinary incontinence after Burch colposuspension failure. <i>International Journal of Urology</i> (2011) 18, 452-457
Song PH, Kim YD, Kim HT, Lim HS, Hyun CH, Seo JH, Yoo ES, Park CH, Jung HC, Gomelsky A. [Pop 306, 7 yr fu] The 7-year outcome of the tension-free vaginal tape procedure for treating female stress urinary incontinence. <i>BJU Int.</i> 2009 Oct;104(8):1113-1117.
Song. [Pop 206, 13 yr fu] AUA Abs. MP33-03 The long-term outcomes from TVT procedure for female SUI; Data from minimal 13 years of follow up; http://www.aula2014.org 2014
Svenningsen R, et al. (Norwegian registry) [Pop 542, median 129 mo fu] Long-term follow-up of the retropubic tension-free vaginal tape procedure. <i>Int Urogynecol J.</i> 2013 Aug;24(8):1271-1278
Svenningsen R. [Pop 810, 10 yr fu] Risk Factors for Long-Term Failure of the Retropubic Tension-Free Vaginal Tape Procedure. <i>Neurourology and Urodynamics</i> (2013) 33:1140-1146
Tamussino K. (Austrian registry) [Pop 2543] Transobturator tapes for stress urinary incontinence: Results of the Austrian registry. <i>Am J Obstet Gynecol</i> 2007;197:634.e1-634.e5.
Tamussino KF, et al. Tension-free vaginal tape operation: Results of the Austrian Registry. <i>Obstet Gynecol</i> 2001; 98:732-736.
Thubert T. [Pop 98, 1 yr fu] Bladder injury and success rates following retropubic mid-urethral sling: TVT EXACT™ vs. TVT™ <i>European Journal of Obstetrics & Gynecology and Reproductive Biology</i> 2016; 198: 78-83
Tincello. The TVT Worldwide Observational Registry for Long Term Data: Safety and Efficacy of Suburethral Sling Insertion Approaches for Stress Urinary Incontinence in Women; <i>The Journal of Urology</i> ; Vol. 186, 2310-2315, December 2011
Tommaselli GA, et al. Medium-term and long-term outcomes following placement of midurethral slings for stress urinary incontinence: a systematic review and metaanalysis. <i>Int Urogynecol J</i> (2015) DOI 10.1007/s00192-015-2645-5
Ulmsten U. A Multicenter Study of Tension-Free Vaginal Tape (TVT) for Surgical Treatment of Stress Urinary Incontinence. <i>Int Urogynecol J</i> 1998; 9:210-213
Ulmsten U. An Ambulatory Surgical Procedure Under Local Anesthesia for Treatment of Female Urinary Incontinence. <i>Int Urogynecol J</i> 1996; 7:81-86
Ulmsten U. Creating a gold standard surgical device: scientific discoveries leading to TVT and beyond. Ulf Ulmsten Memorial Lecture 2014. <i>Int Urogynecol</i> 2015; 26(6): 787-9
Ulmsten U. Intravaginal Slingplasty (IVS): An Ambulatory Surgical Procedure for treatment of Female Urinary Incontinence. <i>Scand J Urol Nephrol</i> 1995; 29:75-82
Unger CA, et al. [Pop 267] Indications and risk factors for midurethral sling revision. <i>Int Urogynecol J.</i> 2015; DOI:10.1007/s00192-015-2769-7.
Valpas, Nilsson. [Pop 121, 5 yr fu] TVT versus laparoscopic mesh colposuspension; 5 year follow-up results of a randomized clinical trial; <i>Int Urogynecol J</i> DOI (2014) 10.1007/s00192-014-2454-2
Ward K. Tension-free vaginal tape versus colposuspension for primary urodynamic stress incontinence: 5-year follow up. <i>BJOG</i> 2008; 115: 226-233
Ward, Hilton. [Pop 344, 5 yr fu IRELAND study] TVT vs colposuspension for primary urodynamic stress incontinence: 5 year follow up. <i>Bjog</i> 2008; 115:226-233
Welk B. (Pop 60K) Removal or Revision of Vaginal Mesh used for the Treatment of Stress Urinary Incontinence. <i>JAMA Surg</i> (2015) Doi:10.1001/jamasurg.2015.2590
Williams TH, TeLinde RW. The Sling Operation for Urinary Incontinence Using Mersilene Ribbon. <i>Obstet Gynecol</i> 1962; 19(2):241-245.

Medical Literature

Young, Rosenblatt, et al. The Mersilene mesh suburethral sling: a clinical and urodynamic evaluation. AJOG 1995; 173:1719-1726.

Production Materials

Document Description [Bates Range]
A Solution-Gynecare TVT Tension-Free Support for Incontinence.
DEPO.ETH.MESH.00004755 - Guidoin Explant
DX23600-R.1-3 - Prolene Resin Manufacturing Specifications 1.23.03
Email string re - Revised write up of the DeLeval and Waltregny visit
ETH.MESH.00071794 - Email re: TVT IFUs on tape extrusion, exposure and erosion
ETH.MESH.00220335-36 - 12.2.1999 Memo re: Biocompatibility Risk Assessment for Soft Prolene Mesh.
ETH.MESH.00262015-016 - Dan Smith Email Plaintiffs Exhibit 2067
ETH.MESH.00349228 - Cytotoxicity Risk Assessment for the TVT (Ulmsten) Device
ETH.MESH.00373310 - Gynecare TVT Tension-Free Support for Incontinence: General Profession Education Deck.
ETH.MESH.00523942 - Waltregny 2005 ICS Presentation
ETH.MESH.00526473-74 - Allison Brown Email re-Laser-cut Mesh
ETH.MESH.00541379-80 - Mesh Fraying for TVT Devices
ETH.MESH.00575257 - Abbrevio laser cut vs. mechanically cut - notes from meeting with de leval - inappropriate
ETH.MESH.00575270-273 - Jean de Leval Email Re: DSCN3332.JPG May 30, 2009
ETH.MESH.00584811-13 - Email string re-Ultrasonic Slitting of Prolene Mesh for TVT
ETH.MESH.00590896-897 - Piet Hinoul Email 3.11.09
ETH.MESH.00658177-198 - Surgeons Resource Monograph
ETH.MESH.00687819-22 - Email string re-Laser cut mesh
ETH.MESH.00857821 - Top Ten Reason to pursue Gynecare TVT Obturator System
ETH.MESH.00858080-081 - Perry Trial - Plaintiff's Exhibit 2313
ETH.MESH.00858096-97 - Gynecare R&D Monthly Update - May
ETH.MESH.00858175-176 - Mulberry Weekly Meeting MINUTES for 6.3.03
ETH.MESH.00858252-53 - 2004 Memo from London Brown to Dan Smith re Mechanical Cut vs. Laser Cut Mesh Rationale
ETH.MESH.00863391 - T-366 - Dan Smith email - particle loss
ETH.MESH.00870466 - Ethicon Expert Meeting-Meshes for Pelvic floor
ETH.MESH.00993273 - TVT Obturator Anatomic Considerations Clinical Update: Special Considerations, Complications.
ETH.MESH.01202189 - Stale Kvitle Email regarding Mini Me follow up from our visit May 20, 2009
ETH.MESH.01202190-191 - David Waltregny Email Re: Mini Me follow up from our visit May 21, 2009
ETH.MESH.01203957-97 - The future of surgical meshes-the industry's perspective
ETH.MESH.01219542-48 - Review of Surgeon Responses of VOC Questionnaire
ETH.MESH.01220135-45 - Email string re-New Standards for Urethral Slings
ETH.MESH.01228079-84 - Nilsson Podcast Transcript
ETH.MESH.01238454-56 - Email string re-TVTO length
ETH.MESH.01279975-976 - Harel Gadot Email re Next step in SUI sling
ETH.MESH.01317508-613 - TVT Factbook DHF - Revised 05.14.2001
ETH.MESH.01752532-35 - Mesh design argumentation issues
ETH.MESH.01784823-28 - Clinical Expert report-Laser Cut Mesh
ETH.MESH.01785259-260 - Email string re: +M relaxation
ETH.MESH.01808311-318 - Trip Report Michael Tracey
ETH.MESH.01809082-83 - Memo re: VOC on new laser cut TVT mesh
ETH.MESH.01813259; ETH.MESH.02180759-61 - Email string with attachment re-Jeans Ideas.
ETH.MESH.01813975-78 - Email string re-FDA Prep-Plaintiff's Exhibit 460

Production Materials

ETH.MESH.01822361-363 - Dan Smith Email regarding TVT Secur October 18, 2006
ETH.MESH.01822361-62 - Dan Smith Email regarding TVT-Secur leading to less retention
ETH.MESH.02017152-56 - 02.23.2007 Ethicon Expert Meeting: Meshes for Pelvic Floor Repair
ETH.MESH.02026591-95 - MSDS-c4001 Polypropylene Homopolymer
ETH.MESH.02090196-209 - Plaintiff's Exhibit 4085-04.15.2008
ETH.MESH.02211890 - Test Report
ETH.MESH.02319312 - Memo re-TVT-base & TVT-O Complaint Review for Laser Cut Mesh Risk Analysis
ETH.MESH.02340331-335 - TVT IFU (12.22.03 to 02.11.05)
ETH.MESH.02340568-90 - TVT-S IFU
ETH.MESH.02340829-835 - TVT-O IFU - (01.07.04 to 03.04.05)
ETH.MESH.02341203-13 - TVT Abbrevio IFU
ETH.MESH.03259439-40 - 4.24.2009 Gauld email chain re Green Journal
ETH.MESH.03427878-883 - TVT IFU - (11.29.10 to 11.26.14)
ETH.MESH.03458123-38 - TVT Patient Brochure
ETH.MESH.03715978 - Weisberg email re: TVT question.
ETH.MESH.03905472-77 - Email string re-TVT recommendation from Dr. Alex Wang
ETH.MESH.03907468-9 - Second Generation TVT - by Axel Arnaud
ETH.MESH.03910175 - Email string re - Soft Prolene
ETH.MESH.03910418-21 - Email string re-Mini TVT - mesh adjustment
ETH.MESH.03911107-08 - Email string re-TVT complications (an Prof. Hausler)
ETH.MESH.03913357-359 - Axel Arnaud Email 5.31.07 Re TVT TVT-O
ETH.MESH.03916905-13 - Plaintiff's Exhibit 3827
ETH.MESH.03924557-86 - Meshes in Pelvic Floor Repair-Findings from literature review and conversations-interviews with surgeons, June 6, 2000.
ETH.MESH.03930120-123 - Nilsson C. Seven-Year Follow-up of the Tension-Free Vaginal Tape Procedure for Treatment of Urinary Incontinence. Obstet Gynecol 2004; 104(6): 1259-62
ETH.MESH.03932909-911 - Confidential - History of TVT-O
ETH.MESH.03932912 - The History of TVT
ETH.MESH.03941623 - DeLeval Email RE: TVT ABBREVO ALERT - French and English Email and English Translation Certification Plaintiff's Exhibit 3619- Perry
ETH.MESH.04048515-520 - Carl Nilsson KOL Interview Project Scion 06.18.08
ETH.MESH.04081189 - Meeting Agenda
ETH.MESH.04082973 - Possible Complications for Surgeries to Correct POP and SUI
ETH.MESH.04092868 - Email re : 10100080654 and TVT IFUs
ETH.MESH.04938298-299 - Piet Hinoul Email Re: Prof. de Leval - TVT Abbrevio
ETH.MESH.04941016 - Lightweight Mesh Developments (Powerpoint)
ETH.MESH.04945231-239 - Email string re-Ultrapro vs Prolene Soft Mesh
ETH.MESH.04945496 - Bernd Klosterhalfen Email Re: Ultrapro vs. Prolene Soft Mesh April 18, 2005
ETH.MESH.05225380-384 - TVT IFU - (09.08.00 to 11.26.03)
ETH.MESH.05337217-220 - Email string, top one from D. Miller to J. Paradise, et al
ETH.MESH.05347751-762 - Email string re Investigator-initiated studied policy
ETH.MESH.05479411 - The (clinical) argument of lightweight mesh in abdominal surgery
ETH.MESH.05479535
ETH.MESH.05588123-126 - Stephen Wohler Email - AW: How inert is polypropylene? July 9, 2007
ETH.MESH.05644163-171 - Pelvic Floor Repair-Surgeon's Feed-back on Mesh Concept
ETH.MESH.05799233-39 - TVT Exact IFU
ETH.MESH.05918776 - Email re: Marlex Experience

Production Materials

ETH.MESH.05958248 - Surgeons Resource Monograph
ETH.MESH.05998835-836 - Piet Hinoul Email Re: ALERTE TVT ABBREVO
ETH.MESH.06592243 - 09.14.2012 Email from Carl Nilsson to Laura Angelini
ETH.MESH.06695438 - Justification for Utilizing the Elasticity Test as the Elongation Requirements on TVT LCM
ETH.MESH.06887138-40 - Waltregny email written on behalf of Professor de Leval.
ETH.MESH.06887244 - 07.16.04 David Waltregny email to Dan Smith re: TVT-O.
ETH.MESH.06917699-704 - Form For Customer Requirements Specification (CRS) For Project TVT-O PA
ETH.MESH.06923868-71 - TVTO-PA Clinical Strategy - 8.21.13 Exhibit A.M. Mitchell T-2177
ETH.MESH.07192929 - Investigating Mesh Erosion in Pelvic Floor Repair Powerpoint
ETH.MESH.07226579-590 - 2000 - TVT CER
ETH.MESH.07383730-31 - Email string re-Ultrapro mesh information-identical mesh to Prolift +M
ETH.MESH.08003181-96 - TVT Patient Brochure
ETH.MESH.08003231-46 - TVT Patient Brochure
ETH.MESH.08003279-94 - TVT Patient Brochure
ETH.MESH.08003295-302 - TVT Patient Brochure
ETH.MESH.08299913-917 - Nilsson C. Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. Int Urogynecol J 2013; 24(8): 1265-9 [9.11.13 Exhibit T-1271]
ETH.MESH.08315779 - Clinical Expert report-09.25.2012
ETH.MESH.08334244; ETH.MESH.08334245 - Email re Photographs of LCM vs MCM with attachments
ETH.MESH.08334244-45 - Email string re-Photographs of LCM vs MCM with powerpoint attachment
ETH.MESH.09264945-46 - Prolene Mesh Re-Design Project
ETH.MESH.09630649 - 4.26.1973 FDA Letter RE: NDA 16-374
ETH.MESH.09656792
ETH.MESH.09656795
ETH.MESH.09744858-63 - TVT Patient Brochure
ETH.MESH.09746948-998 - License and Supply Agreement [Rosenzweig Exhibit 21 - 12.22.15]
ETH.MESH.09747038-097 - Medscand Agreement
ETH.MESH.09747337-369 - Asset Purchase Agreement
ETH.MESH.09888187-223 - Seven Year Data for Ten Year Prolene Study - Plaintiff's Exhibit 4102
ETH.MESH.09922570-578 - R&D Memorandum of PA Mesh Assessments for TVTO-PA Revision 1
ETH.MESH.10281860 - Tension-Free Midurethral Sling: Market Update.
ETH.MESH.11336474-87 - Ten Year In Vivo Suture Study Scanning Electron Microscopy-5 Year Report - Plaintiff's Exhibit 4111
ETH.MESH.12831391-92 - P4128 - IR Microscopy of Explanted Prolene received from Prof. R. Guidoin.
ETH.MESH-08476311 - Cytotoxicity assessment of Ulstem sling
Gynecology Solutions
Johnson & Johnson - Our Credo [8.9.13 A.M. Mitchell Exhibit T-3134]
June, 2009 Klosterhalfen intermediate report on explanted mesh (highlighted)
Klinge Presentation PVDF: a new alternative? Meeting o Hernia Experts Exhibit P-1944
Librojo updated TVT Declaration (10-23-15) [12 pages]
McCabe email re - Sheath Sales Tool - 464
MSDS-Marlex Polypropylenes
P4122 - SEM Figure 183: Sample J7959 13409 (Photographs)
Payments to Medscand [9.16.13 Exhibit T-3192]
Payments to Medscand by J&J [9.16.13 Exhibit T-3183]
Payments to Ulmsten as Consultant [9.16.13 Exhibit T-3204]

Production Materials

Published clinical data and RCTs - Ethicon.com - 4204-C
Seven Year Dog Study - T-2263
TVT Abbrevio IFU - 01.2015
TVT Exact IFU - 01.2015
TVT IFU - 01.2015
TVT Patient Brochure - 2015
TVT-O la bandelette trans-obturatrice (Photograph)
TVT-Obturator IFU - 01.2015

Company Witness Depositions

Deponent [Date of Deposition]
Hinoul, Piet - 04.05.2012 Deposition Testimony
Hinoul, Piet - 09.18.2012 Deposition Testimony
Weisberg, Martin - 05.24.2012 Deposition Testimony
Weisberg, Martin - 8.9.2013 Deposition Testimony
Weisberg, Martin - 11.12.2015 Deposition Testimony
Weisberg, Martin - 11.13.2015 Deposition Testimony
Nager, Charles - 06.10.2014 Deposition Testimony

Other Materials

Publically Available
24 Hour Summary of the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee Meeting [02.26.2016].
FDA - Device Labeling Guidance #G91-1 March 1991
FDA Considerations about Surgical Mesh for SUI [03.27.2013].
FDA Executive Summary: Surgical mesh for treatment of women with POP and SUI [09.08.2011]
FDA News Release: Surgical Placement of mesh to repair pelvic organ prolapse poses risk [07.13.2011].
FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surigical Mesh in Repair of POP and SUI. Issued: 10.20.2008.
FDA Questions: Reclassification of the Urogynecologic Surgical Mesh Instrumentation.
Device Labeling Guidance
Deposition Subject Matter-Design and Development of Mesh Products
Oxford Levels of Evidence; www.cebi.ox.ac.uk/fileadmin/_processed_/csm_Evidence_pyramid_bluef5c85529a0.jpg
AUA Guideline for the Surgical Management of Female Stress Urinary Incontinence Update (2009)
ACOG, AUGS Practice Bulletin Summary of 155 (replaces 63 from 2005) Urinary Incontinence in Women. November 2015.
AUGS SUFU Position Statement on MUS for SUI
AUGS SUFU Frequently Asked Questions by Patients MUS for SUI
AUGS SUFU Frequently Asked Questions by Providers MUS for SUI
AUGS Position Statement on Restrictions of Surgical Options for Pelvic Floor Disorders
AUA (2011) - Position Statement on the Use of Vaginal Mesh for SUI
FDA Considerations about Surgical Mesh for SUI
IUGA Position Statement on MUS for SUI (2014)
IUGA Mid-urethral sling (MUS) procedures for stress incontinence (2011)
2013 Sept. NICE 171 Guideline - The management of urinary incontinence in women
ICS Fact Sheet 2015
RANZOG and UGSA 2014 Position Statement
2012 ABOG - Guide to Learning in Female Pelvic Medicine and Reconstructive Surgery
AUA National Medical Student Curriculum Urinary Incontinence
AUGS Resident Learning Objectives
ACGME Program Requirements.

Betty McCumber - Case Specific

Depositions
McCumber, Betty - 4.11.2017
Expert Reports
Other
Medical Records
Adena Health Systems - Billing 1-7
Adena Medical Group - Billing 1-9
Adena Regional Medical Center - Pathology 1-2
Adena Regional Medical Center - Radiology 1-1
Adena Regional Medical Center - Radiology 2-2
Adena Urology - Billing 1-7
Adena Urology - Billing 8-16
Adena Urology - Medical 1-5
Adena Urology - Medical 17-17 (cert)
Adena Urology - Medical 6-6 (cert)
Adena Urology - Medical 7-16
Baker Joyce LPC - Medical 1-1 NRS
Centers for Medicare & Medicaid - Insurance NR cert or letter 1-1
Centers for Medicare & Medicaid - Insurance NR cert or letter 2-3
Haller Marla D DO - Medical 1-2 NRS
Holzer Clinic - Medical 1080-1101
Holzer Clinic - Medical 1-256
Holzer Clinic - Medical 251-515
Holzer Clinic - Medical 516-1079
Holzer Medical - Billing 10-14
Holzer Medical - Billing 1-9
Holzer Medical Center - Billing 15-16
Holzer Medical Center - Medical 137-191
Holzer Medical Center - Medical 1-93
Holzer Medical Center - Medical 94-136
Holzer Medical Center - Medical cert 192-192
Holzer Medical Center - Pathology 1-1 NRS
Holzer Medical Center - Radiology 1-24
Holzer Medical Center - Radiology 25-27
Kincaid Stephen Craig Dr - Medical 1-134
Kings Daughters Family Care - Medical 1-31
Kings Daughters Family Care - Medical 132-132
Kings Daughters Family Care - Medical 133-719

Betty McCumber - Case Specific

Kings Daughters Family Care - Medical 32-90
Kings Daughters Family Care - Medical 720-769
Kings Daughters Family Care - Medical 770-844
Kings Daughters Family Care - Medical 91-131
Kings Daughters Family Care Centers - Billing 845-874
Nooranissa J Pasha MD - Medical 1-1 NRS
Ohio Health Heart And Vascular Physicians - Medical 1-1
Ohio Health Physician Group - Billing 1-1
Plaintiff Profile Form 1-5
Plaintiff Profile Form 6-10
Plaintiff Supplied Records - 198-294
Plaintiff Supplied Records 100-197
Plaintiff Supplied Records 1-1
Plaintiff Supplied Records 2-99
Shriver Family Practice - Medical 1-17
Shriver Family Practice - Medical 18-18 CER
Shriver Family Practice - Medical 19-19 CER
Southern Ohio Medical Center - Billing 1-1 NRS
Southern Ohio Medical Center - Medical NR cert or letter 1-1
Southern Ohio Medical Center - Pathology 1-1 NRS
Southern Ohio Medical Center - Radiology 1-1
SSA Retirement and Disability - 1-290
SSA Retirement and Disability - 291-592